

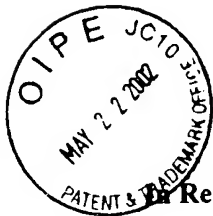
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DOCKET NO.: ISIS-4947

MAY 24 2002

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Gregory E. Hardee, et al.

Serial No.: 10/071,822

Group Art Unit: 1635

Filing Date: February 8, 2002

Examiner: Not Yet Assigned

For: MULTIPARTICULATE FORMULATION

DATE OF DEPOSIT: MAY 10, 2002  
I HEREBY CERTIFY THAT THIS PAPER IS BEING  
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THE ASSISTANT COMMISSIONER FOR PATENTS,  
WASHINGTON, DC 20231.

TYPED NAME: Emma R. Dailey  
REGISTRATION NO.: 48,491

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- ☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first office action after the filing of request for continued examination under §1.114, no additional fee is required.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☒ In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:

☒ Copies of references AA-BO listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/256,515, filed February 23, 1999.

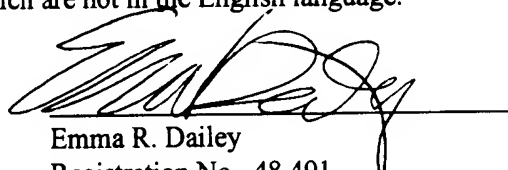
☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: May 10, 2002

  
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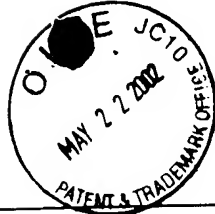
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>ISIS-4947</b>	Serial No. <b>10/071,822</b>
		Applicant <b>Gregory E. Hardee, et al.</b>	
		Filing Date <b>February 8, 2002</b>	Group <b>1635</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AA	Ayniè, I., et al., "Alignate nanoparticles as a noval carrier for antisense oligonucleotides," <i>Future Strategies Drug Delivery Part. Syste., Lect. Eur. Workshop Part. Syst. 1<sup>st</sup></i> , <b>1988</b> , 11-16	
	AB	Ayniè, I., et al., "Role of a small polylysine in a hydrogel nanoparticulate system for the antisense oligonucleotide delivery strategy," <i>Proc. 2<sup>nd</sup> World Meeting APGI/APV</i> , <b>1988</b>	
	AC	Balland, O., et al., Nanoparticles as carriers for antisense oligonucleotide," <i>Targeting of Drugs 5: Strategies for Oligonucleotide and Gene Delivery in Therapy</i> , <b>1996</b> , 131-142	
	AD	Berton, M., et al., "Poly(D,L-Lactic acid) nanoparticles as phosphorothiate oligonucleotide carriers in U937 cells," <i>Proc. 2<sup>nd</sup> World Meeting APGI/APV</i> , <b>1998</b>	
	AE	Cleek, R., et al., "Inhibition of smooth muscle cell growth in vitro by an antisense oligodeoxynucleotide released from poly(DL-lactic-co-glycolic acid) microparticles," <i>J. Biomed. Mater. Res.</i> , <b>1997</b> , 35, 525-530	
	AF	Fasano, A., "Novel approaches for oral delivery of macromolecules," <i>J. Pharm. Sci.</i> , <b>1998</b> , 87(11), 1351-1356	
	AG	Fattal, E., et al., "Nanoparticles and liposomes for drug targeting," <i>Future Strategies Drug Delivery Part. Syste., Lect. Eur. Workshop Part. Syst. 1<sup>st</sup></i> , <b>1998</b> , 1-4	
	AH	Fritz, H., et al., "Cationic polystyrene nanoparticles: preparation and characterization of a model drug carrier system for antisense oligonucleotide," <i>J. Colloid Interface Sci.</i> , <b>1997</b> , 195, 272-288	
	AI	Gaspar, R., "Drug targeting using poly(alkyl cyanoacrylate) (PACA) nanoparticles," <i>Rev. Port. Farm.</i> , <b>1991</b> , 41(3), pages 36-38, 40-42, 44-45	
	AJ	Kawashima, Y., et al., "Mucoadhesive DL-lactide/glycolide copolymer nanospheres to improve oral delivery of elcatonin," <i>Proc. 2<sup>nd</sup> World Meeting APGI/APV</i> , <b>1998</b>	
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		Filing Date <b>February 8, 2002</b>	Group <b>1635</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	AK	Lewis, K., et al., "Biodegradable poly(L-lactic acid) matrices for the sustained delivery of antisense oligonucleotides," <i>J. Controlled Release</i> , <b>1995</b> , 37, 173-183	
	AL	Vauthier, C., et al., "Pharmacokinetic and tissue disposition of oligonucleotides associated with alginate nanoparticles," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , <b>1998</b> , 25, 228-229	
	AM	Zimmer, A., et al., "Cationic nanoparticles as enhancers for cellular uptake of antisense oligonucleotides," <i>Proceed. Int'l Symp. Control. Rel. Bioact. Mater.</i> , <b>1997</b> , 24, 679-680	
	AN	Zobel, H.P., et al., "Cationic polyhexylcyanoacrylate nanoparticles as carriers for antisense oligonucleotides," <i>Antisense Nucleic Acid Drug Dev.</i> , <b>1997</b> , 7, 483-493	
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List of Patent and Publications  
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U.S. Department of Commerce  
Patent and Trademark Office

Docket No.  
**ISIS-4947**

Serial No.  
**10/071,822**

Applicant  
**Gregory E. Hardee, et al.**

Filing Date  
**February 8, 2002**

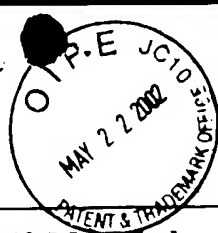
Group  
**1635**

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	AO	5,405,621	04/11/95	Sipos	424	490
	AP	5,460,831	10/24/05	Kossovsky, et al.	424	493
	AQ	5,498,421	03/12/96	Grinstaff, et al.	424	450
	AR	5,503,852	04/02/96	Steiner, et al.	424	493
	AS	5,554,388	09/10/96	Illum	424	501
	AT	5,690,954	11/25/97	Illum	424	434
	AU	5,744,166	04/28/98	Illum	424	501
	AV	5,783,567	07/21/98	Hedley	514	44
	AW	5,795,587	08/18/98	Gao	424	450
	AX	6,001,395	12/14/99	Coombes, et al.	424	501

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	AY	0 599 282 A1	06/01/94	EPO		
	AZ	0 508 312 B1	09/18/96	EPO		
	BA	0 509 335 B1	08/21/96	EPO		
	BB	0 516 141 B1	08/14/96	EPO		
	BC	WO 88/09163	12/01/88	PCT		
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				Applicant <b>Gregory E. Hardee, et al.</b>			
				Filing Date <b>February 8, 2002</b>		Group <b>1635</b>	
<b>U. S. PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	
<b>FOREIGN PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Translation YES NO</b>		
	<b>BD</b>	WO 92/21330	12/10/92	PCT			
	<b>BE</b>	WO 97/03702	02/06/97	PCT			
	<b>BF</b>	WO 97/04747	02/13/97	PCT			
	<b>BG</b>	WO 97/12618	04/10/97	PCT			
	<b>BH</b>	WO 97/32572	09/12/97	PCT			
	<b>BI</b>	WO 98/00169	01/08/98	PCT			
	<b>BJ</b>	WO 98/04719	02/05/98	PCT			
	<b>BK</b>	WO 98/12987	04/02/98	PCT			
	<b>BL</b>	WO 98/29099	07/09/98	PCT			
	<b>BM</b>	WO 98/29557	07/09/98	PCT			
	<b>BN</b>	WO 98/48626	11/05/98	PCT			
	<b>BO</b>	WO 98/49348	11/1998	PCT			
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			